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Pauline Ann Clarke  
Syntex (U.S.A.) Inc., Patent Law Dept. A2-200  
3401 Hillview Ave.  
P.O. Box 10850  
Palo Alto, CA 94303

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,753,935

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,753,935, filed January 30, 1987 and issued June 28, 1988, which claims the human drug product CELLCEPT® (mycophenolate mofetil), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 824 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of December 7, 1995. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,304) + 175 \\ &= 1327 \text{ days}\end{aligned}$$

Since the regulatory review period began July 21, 1988, after the patent issued (June 28, 1988), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14-year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (May 3, 1995) when added to the period of extension calculated above (1327 days) cannot exceed fourteen years. The period of extension is thus limited to May 3, 2009, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of twenty-years from filing (35 U.S.C. § 154) would expire on January 30, 2007, the period of extension is the number of days to extend the term of the patent from its expiration date to and including May 3, 2009, or 824 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 824 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,753,935
Granted:	June 28, 1988
Applicant:	Peter H. Nelson et al.
Owner of Record:	Syntex (U.S.A.) Inc.
Title:	Morpholinoethylesters of Mycophenolic Acid and Pharmaceutical Compositions
Classification:	514/233.5
Product Trade Name:	CELLCEPT®
Term Extended:	824 days

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



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Hiram H. Bernstein  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: CELLCEPT®  
FDA Docket No.: 95E-0300